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**Filed** : February 20, 2004

## **REMARKS**

By way of summary, Claims 1-30 are pending in this application. Claims 1, 12 and 16 have been amended. In the outstanding Office Action of March 8, 2007, the Examiner acknowledged certain Information Disclosure Statements, rejected Claims 1 and 9-10 under 35 U.S.C. §102(a) as being anticipated by Gifford (U.S. Pub. No. 2004/0267191), and rejected Claims 2-8 and 11-30 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of six other references.

### **I. Claim Amendments**

In this Amendment, Claims 1, 12 and 16 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

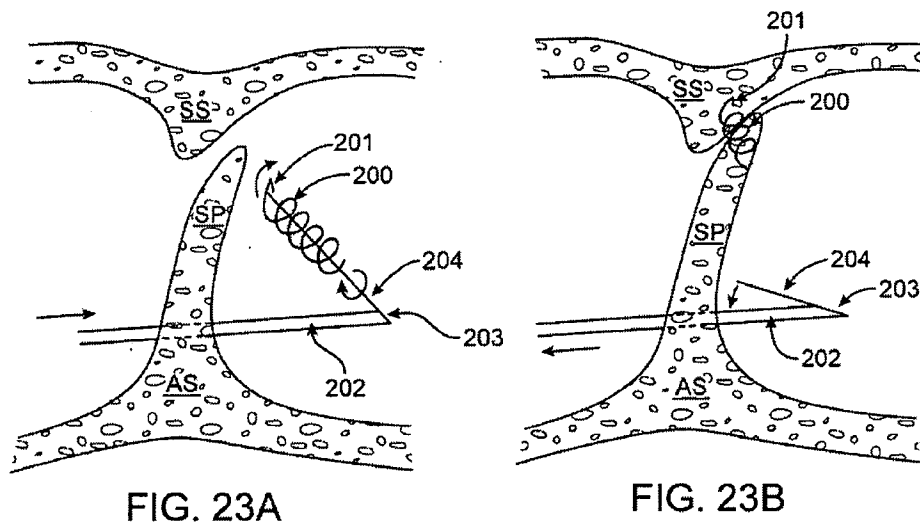
### **II. § 102(a) Claim Rejection**

#### **A. Amended Independent Claim 1 is not anticipated nor rendered obvious by Gifford**

Applicant disagrees with the Examiner's application of Gifford as prior art under 102(e) to the extent that the provisional applications to which Gifford claims priority do not describe and enable an embodiment corresponding to Figures 23A-23B and paragraph 98 of Gifford. MPEP §2121.01 discusses the standard for the use of prior art in rejections where operability is in question: "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo*

*Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).

Nevertheless, Gifford discloses methods and apparatus for treatment of a patent foramen ovale (PFO) with embodiments using a retractable abrasive needle from a catheter, advancing the needle through the PFO and/or tissue adjacent to the PFO, and retracting the needle relative to the PFO to abrade at least a portion of the tissue. Gifford Abstract. The Examiner cites one particular embodiment of Gifford's needle with reference to figures 23A and 23B and paragraph [0098]: these are reproduced here for the Examiner's convenience:



At paragraph [0098], Gifford states (with Examiner's characterizations in parentheses):

"...a PFO a spiral needle 200 ("coil") may be applied to tissue adjacent the PFO to close the PFO, from a position within the left atrium. As shown in FIG. 23A, in one embodiment, a catheter 202 ("outer catheter") is delivered through the atrial septum AS, with spiral needle 200 ("coil") and a retractable delivery arm 204 ("elongate body") retracted within catheter 202 ("outer catheter"). Once a distal portion of catheter 202 ("outer catheter") is positioned in the left atrium, delivery arm 204 ("elongate body") may be extended from catheter 202 ("outer catheter") about a universal joint 203. Catheter 202 ("outer catheter") may then be turned, twisted or torqued to drive spiral needle 200 ("coil") off of delivery arm 204 ("elongate body") and into tissue adjacent the PFO. In one embodiment, as shown, spiral needle 200 ("coil") is driven into and through septum primum SP tissue and into septum secundum SS tissue to bring the two tissues together. A hook or barb 201 on spiral needle 200 ("coil") helps hold needle 200 ("coil") in place within tissue. As shown in FIG. 23B, when spiral needle 200 ("coil") is in place, it pulls together septum primum SP and septum secundum SS. Retractable delivery arm 204 ("elongate body") is then retracted within catheter 202 ("outer catheter"), and catheter 202 ("outer catheter") is withdrawn."

The Applicant does not recognize what the Examiner is characterizing as a tissue piercing structure within the Gifford reference. In making the rejection, the Examiner states, in part, "Gifford discloses ... the elongate body having a tissue piercing structure at its distal end" without identifying any structure within Gifford that would correspond to a tissue piercing structure. Gifford does not disclose a tissue piercing structure at the distal end of Gifford's "elongate body" 204. As disclosed in paragraph [0098], the delivery arm 204 is described as retractable and extendable from a catheter 202 from a universal joint 203 after the catheter somehow extends through a hole at or below the PFO. There is no description of the distal end of the delivery arm. The figures show a barb 201 at the distal end of the spiral needle 200, but that is the only structure described which is shown to pierce any tissue. As described in Gifford's specification and as shown in Gifford's figures, the distal end of the delivery arm 204 does not pierce any tissue in the septum primum SP tissue or the septum secundum SS tissue. Instead, the catheter 202 turns, twists or torques the spiral needle 200 off the delivery arm 204. Once the needle 200 is delivered, the delivery arm 204 is retracted back into the catheter 202 and the catheter 202 is withdrawn, leaving what would appear to be a hole in the in or below the septum primum (SP) where the catheter 202 is withdrawn.

Independent Claim 1 has amended the claims in order to clarify certain features of Applicant's claimed invention. Figures from the Applicant's application include:

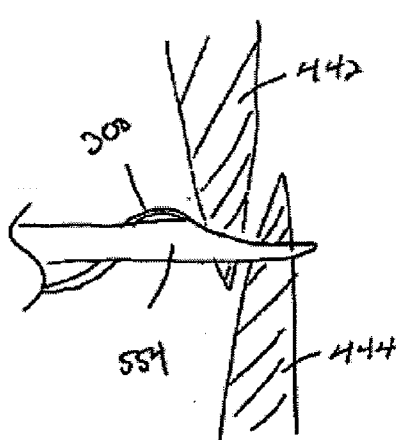


FIG. 11

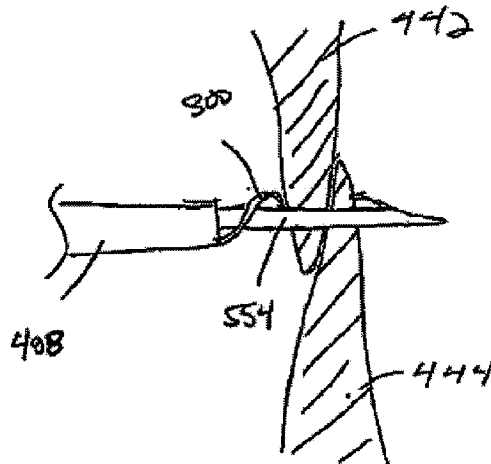


FIG. 12

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In contrast to the disclosure and teachings of Gifford, amended independent Claim 1 recites, in part, “advancing the tissue piercing structure and the coil through the septa of the patent foramen ovale, wherein both the tissue piercing structure and the coil extend into the septum primum and the septum secundum.” As discussed above, Gifford does not have a separate tissue piercing structure that extends in the septum primum and septum secundum. Instead it drives a barb 201 which is part of the distal end of the spiral needle 200 into the PFO. Nowhere does Gifford disclose that part of the elongate member or delivery arm 204 pierces, enters, or comes into contact with tissue while it is extended in the left atrium or retracted within the catheter 200. Furthermore, the delivery arm 204 does not “extend in the septum primum and the septum secundum.” Accordingly, Applicant respectfully submits that independent Claim 1 is not anticipated nor rendered obvious by Gifford and respectfully requests that the anticipation rejections based on Gifford be withdrawn.

Claims 9 and 10 depend from Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to amended Claim 1, Applicant respectfully submits that Claims 9 and 10 are patentable over Gifford. Claims 9 and 10 also are patentable over Gifford in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 1, 9 and 10 based on Gifford.

### **III. § 103(a) Claim Rejections**

From an initial standpoint, all of the Examiner’s 35 U.S.C. §103 claim rejections include Gifford. As expressed above, Applicant disagrees with the Examiner's application of Gifford as prior art to the extent that the provisional applications to which Gifford claims priority do not describe and enable an embodiment corresponding to Figures 23A-23B and paragraph 98 of Gifford.

#### **A. Claims 2 and 11-19 are not rendered obvious over Gifford in view of Pierson, III (“Pierson”) (U.S. 6,663,633);**

The outstanding Office Action rejected Claims 2 and 11-19 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of Pierson. Applicant asserts that one skilled in the art would not have found a reason to combine Gifford with Pierson, and that the Examiner has not

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explicitly articulated any reason why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicant.

The Supreme Court's decision on *KSR Int'l. v. Teleflex, Inc.* refines the issue of obviousness under 35 U.S.C. §103(a) in relation to prior art. *KSR Int'l. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). The Court noted that the analysis supporting a rejection under 35 U.S.C. §103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements: in the manner claimed. The Court specifically stated:

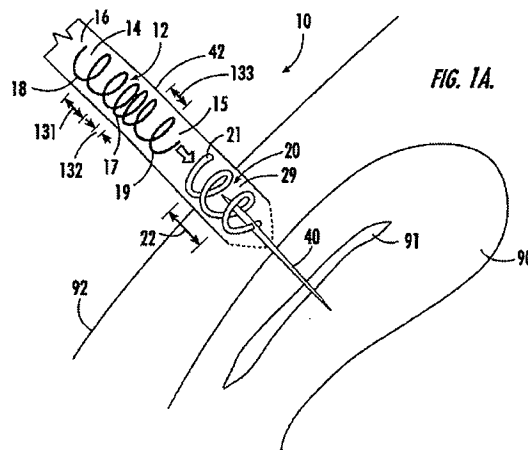
Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

*KSR*, slip op. at 14 (emphasis added). Therefore, in making a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, Applicant submits that the Examiner must expressly identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. Beyond the conclusory statements made in the Office Action, the Examiner has failed to do so.

Applicant further submits that one skilled in the art would not look to Pierson to modify a PFO method as in Gifford, because Pierson is directed to orthopedic procedures for fixating soft tissue tears (such as tears in the menisci of the knee) or bone fractures reduction. Pierson col. 1, ll. 8-16, and 23. Although it is not dispositive that Pierson is in a different field of endeavor, the modifications proposed by the Examiner involves more than just ordinary skill or common sense in order to make the modification operable. Specifically with respect to Claim 12, Gifford teaches a delivery arm 204 that carries a single spiral needle 200, and one skilled in the art would not understand from Pierson or his own knowledge how to modify Gifford in an operable way to deliver a plurality of coils using the same delivery arm. The PFO environment is much different

from the orthopedic environment, and it goes beyond just a combination of known elements to produce the claimed invention.

Dependent Claims 2 and 11 depend from amended Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1 as well as the lack of an explicit reason to combine Gifford in view of Pierson, Applicant respectfully submits that Claims 2 and 11 are patentable over Gifford in view of Pierson. Claims 2 and 11 are also are patentable over Gifford in view of Pierson in view of the additional limitations recited in each of the claims. For example, Applicant does not recognize what the Examiner characterizes as an opening in stating “Pierson teaches an elongate body 40 having an opening near its distal end (Figure 1A).” Office Action p. 4. The floating needle 40 illustrated in Figure 1A has no opening at or near its distal end.



Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 2 and 11 based on Gifford in view of Pierson.

Independent Claim 12 has been amended in order to clarify certain features of Applicant's claimed invention. In contrast to the disclosure and teachings of Gifford, amended independent Claim 12 recites, in part, "releasably engaging a plurality of coils with a single delivery device, advancing the single delivery device carrying the plurality of coils into a patient to a location proximate the patent foramen ovale." Gifford does not teach or suggest "releasably engaging a plurality of coils with a single delivery device, advancing the single delivery device carrying the plurality of coils into a patient to a location proximate the patent foramen ovale." Furthermore, there is no apparent reason for one to practice Applicant's Claim 12 given Gifford's disclosure.

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and the Examiner has not explicitly described why or how one skilled in the art would combine the retractable delivery arm and catheter driving mechanism for deploying needles in Gifford with Pierson. In fact, as discussed above, one skilled in the art would not make such a combination. Accordingly, Applicant respectfully submits that independent Claim 12 is not anticipated nor rendered obvious by Gifford in view of Pierson and respectfully requests that the anticipation rejections based on Gifford in view of Pierson be withdrawn.

Dependent Claims 13-19 depend from Claim 12 and further define the invention of Claim 12. For at least the reasons set forth above with respect to amended Claim 12, Applicant respectfully submit that Claims 13-19 are patentable over Gifford in view of Pierson. Claims 13-19 are also are patentable over Gifford in view of Pierson in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 12-19 based on Gifford in view of Pierson.

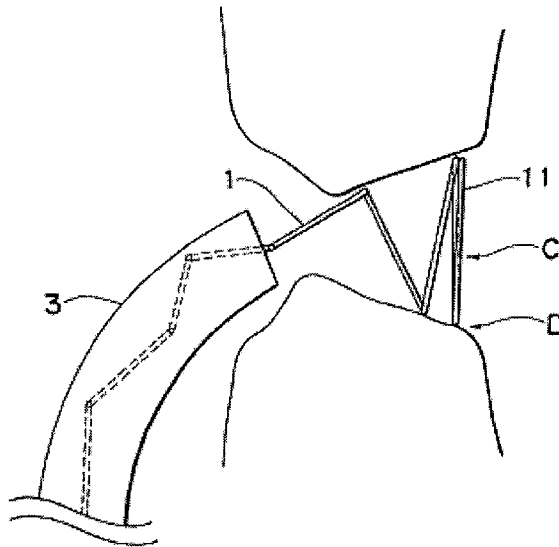
**B. Independent Claim 20 is not rendered obvious over Gifford in view of Kobayashi (U.S. 6,375,671);**

The outstanding Office Action rejected Claims 20, 21, 26 and 29 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of Kobayashi. Furthermore, Claims 22 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi in further view of Kay (U.S. 5,662,683). Claim 23 was also rejected under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi and Kay in further view of Pierson. Claims 24-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi in further view of Pierson. Claims 27-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi in further view of Bolduc (U.S. 5,582,616). Claim 30 was rejected under 35 U.S.C. §103(a) as being unpatentable over Gifford and Kobayashi in further view of Pierson.

Applicant asserts that one skilled in the art would not have found a reason to combine Gifford with Kobayashi, and that the Examiner has not explicitly articulated any reason why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicant. As discussed above with respect to *KSR Int'l. v. Teleflex, Inc.*, in formulating a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

One skilled in the art would also not look to Kobayashi to modify a PFO method as in Gifford, because Kobayashi is directed to closure devices with relatively large-sized circular portions for closing open septal defects. Kobayashi Abstract and all Figures.

*Fig. 6*



Kobayashi does not refer to a PFO, which as Gifford describes, has a flap and a patent channel. Gifford p. 1, para. [0004]. Instead, Kobayashi is directed to open holes in the septa which use “relatively large-sized circular portions” to occlude the septal defects, in which “the flap of tissue is missing” as is described in Gifford p. 1, para. [0004]. In order to have the Gifford method and device operable, the spiral needle must secure one flap into parallel tissue: “the spiral needle 200 (“coil”) is driven into and through septum primum SP tissue and into septum secundum SS tissue to bring the two tissues together.” Gifford p. 10, para. [0098]. Although it is not dispositive that Kobayashi is in a different field of endeavor, the modification proposed by the Examiner involves more than just ordinary skill or common sense in order to make the modification operable. Specifically, Gifford teaches a single spiral needle 200, that is driven into and through septum primum SP tissue and into septum secundum SS tissue to bring the two tissues together, and one skilled in the art would not understand from Kobayashi or his own knowledge how to modify Gifford in an operable way to attach a flap to overlapping tissue that is not present in an open septal defect. The application of a spiral needle to an open septal defect would not be likely to be therapeutic and would likely increase damage to the heart.



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Further, even if the references were combined, Gifford and Kobayashi fail to produce the claimed embodiment of Applicant's invention. Applicant disagrees with the Examiner's characterization of what Gifford and Kobayashi teach. For example, the Examiner states "Gifford discloses the claimed device, including a loading portion 204 adapted to releasably engage a distal end of a coil 200." Office Action p. 8. Gifford does not disclose a loading portion. Object 204 is a deployment arm and Gifford provides no description as to how, or even if, the deployment arm 204 is attached to the spiral needle 200. Gifford states that "Catheter 202 ("outer catheter") may then be turned, twisted or torqued to drive spiral needle 200 ("coil") off of delivery arm 204 ("elongate body") and into tissue adjacent the PFO." There is no disclosure of a loading portion as claimed in the Applicant's claim.

The Examiner also states that Gifford discloses "a distal structure (distal end of coil 200) adapted to releasably engage a distal end of the coil 200 using a tissue piercing structure that is integral with the tissue piercing structure." Office Action p. 8-9. The Applicant is unable to understand how the characterized "tissue piercing structure"—which, as described above, is not disclosed in Gifford—is attached to the spiral needle or how the Examiner characterizes it as engaging the distal end of the coil 200. It is not clear how Gifford uses "a tissue piercing structure that is integral with the tissue piercing structure." Office Action p. 8-9.

Furthermore, the Examiner also states that "Kobayashi teaches a loading portion 4 ... holding the coil relative to the piercing structure." Kobayashi does not disclose any tissue piercing structures. The Kobayashi device operates within open septal defects and has no part of its device pierce tissue. In fact, neither Gifford nor Kobayashi, alone or in combination, teach holding a coil "to axially elongate and radially reduce the coil," as required by Applicant's Claim 20. Therefore, the Examiner has not articulated any proposed combination of the references that satisfies the limitations of Claim 20.

Applicant respectfully submits that independent Claim 20 is not anticipated nor rendered obvious by Gifford in view of Kobayashi and respectfully requests that the anticipation rejections based on Gifford in view of Kobayashi be withdrawn. Dependent Claims 21, 26 and 29 depend from Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submit that Claims 21, 26 and 29 are patentable over Gifford in view of Kobayashi. Claims 21, 26 and 29 are also are patentable over

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Gifford in view of Kobayashi in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 20, 21, 26 and 29 based on Gifford in view of Kobayashi.

**C. Dependent Claims 3 and 4 are not rendered obvious over Gifford and Pierson in view of Johnson (U.S. 6,485,504);**

The outstanding Office Action rejected Claims 3 and 4 under 35 U.S.C. §103(a) as being unpatentable over Gifford and Pierson in view of Johnson. Dependent Claims 3 and 4 depend from amended Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1 as well as the lack of an explicit reason to combine Gifford in view of Pierson, Applicant respectfully submit that Claims 3 and 4 are patentable over Gifford and Pierson in view of Johnson. Claims 3 and 4 are also are patentable over Gifford and Pierson in view of Johnson in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 3 and 4 based on Gifford and Pierson in view of Johnson.

**D. Dependent Claims 5-7 are not rendered obvious over Gifford in view of Laufer (U.S. Pub. 2004/0193194);**

The outstanding Office Action rejected Claims 5-7 under 35 U.S.C. §103(a) as being unpatentable over Gifford in view of Laufer. Dependent Claims 5-7 depend from amended Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicant respectfully submit that Claims 5-7 are patentable over Gifford in view of Laufer. Claims 5-7 are also are patentable over Gifford in view of Laufer in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 5-7 based on Gifford in view of Laufer.

**E. Dependent Claim 8 is not rendered obvious over Gifford and Laufer in view of Johnson (U.S. 6,485,504);**

The outstanding Office Action rejected Claim 8 under 35 U.S.C. §103(a) as being unpatentable over Gifford and Laufer in view of Johnson. Dependent Claim 8 depends from amended Claim 1 and further defines the invention of Claim 1. For at least the reasons set forth

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above with respect to Claim 1, Applicant respectfully submit that Claim 8 is patentable over Gifford and Laufer in view of Johnson. Claim 8 is also patentable over Gifford and Laufer in view of Johnson in view of the additional limitations recited in its claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 8 based on Gifford and Laufer in view of Johnson.

#### **IV. Conclusion**

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or prior art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, she is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: JUNE 8, 2007

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